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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,997	06/23/2000	IMRE KOVESDI	204526	8984

23460 7590 01/24/2003

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/24/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/599,997

Applicant(s)

KOVESDI ET AL.

Examiner

Terry A. McKelvey

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 December 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires three months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☒ Newly proposed or amended claim(s) 13-14 (if amended to be independent claims with all of the limitations as proposed) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: 13 and 14.

Claim(s) rejected: 1,3-12,15,18-21 and 24-27.

Claim(s) withdrawn from consideration: 16,17,22 and 23.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Terry A. McKelvey
Terry A. McKelvey
Primary Examiner
Art Unit: 1636

Continuation of 2. NOTE: For example, the proposed amendment attempts to place new limitations in claim 1 (replication deficient and lacking E1 and E4) that would result in dependent claims, such as claim 4, to have combinations of claim limitations which were not previously examined, requiring further consideration and/or search and requiring changes to the art rejections of record.

Continuation of 3. Applicant's reply has overcome the following rejection(s): claims 13 and 14 rejected under 35 USC 103(a) over Bouck et al and Cuthbertson in view of Brough et al and Brough et al.

Continuation of 5. does NOT place the application in condition for allowance because: the rejections remain of record due to the non-entry of the proposed amendment and the non-persuasive nature of (most of) the applicant's arguments. The applicant's arguments are addressed only in so far as they apply to the rejections of the unamended claims of record. The applicant is essentially arguing that because the Bouck and Cuthbertson references teach various alternatives not specifically directed to the claimed invention that these teachings teach away from the claimed invention because the references must be considered as a whole. This argument is completely not persuasive because considering a reference in its entirety entails considering everything that the reference teaches, including alternatives and anything specifically negative concerning the claimed invention. "Teaching away" is when a reference specifically teaches that something doesn't work or has problems that make that something undesirable. In the instant case, the references specifically teach alternatives that make obvious the claimed invention. There is no teaching away that the claimed invention would not work or is clearly undesirable. For example, Bouck et al clearly teaches that adenovirus is one of the suitable vectors for practicing his invention drawn to administration of SLED nucleic acid for disease treatment. In no way can the reference be properly construed as teaching away from using adenovirus vectors just because additional suitable alternatives are taught. The obviousness of the combination of the cited references was specifically addressed in the rejections of record and except for the argument addressed above, was not specifically addressed by the applicant's arguments. The applicant argues that the Wickham reference does not satisfy the alleged deficiencies of the Bouck reference and the Cuthbertson reference (regarding the obviousness of the combination of these two references). This argument is not drawn to what Wickham is relied upon in the rejection and is not persuasive for reasons of record because this argument was already addressed in the office action mailed 10/22/02, paper no. 11, at pages 16-17. The applicant argues that it is improper under 35 USC 103(c) to cite the Brough patents because they only qualify in the 102(e) sense and that they are commonly owned. This argument is only persuasive for claims 13-14 for the following reasons. 35 USC 103(c) states that "Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." It is agreed that the claimed subject matter of claims 13-14 should be disqualified under 103(c) because these claims contain limitations which are drawn to subject matter in the Brough patents which is claimed and thus not drawn to prior art disclosures of the Brough patents. The remaining teachings relied upon from the Brough patents, drawn to adenovirus deletions in E1, E2, E3, and/or E4, and use of LCR-type cis-acting sequences in adenoviruses and CMV promoter (not in combination with all of the limitations of claims 13-14) do not qualify as subject matter developed by Brough et al (and the assignee) owned by Brough et al (the assignee) because these teachings are merely teachings in the Brough patents of well known prior art as evidenced by the attached references which show that these limitations were obvious based upon prior art not owned by the assignee of Brough et al. In no way can these teachings of prior art set forth in the Brough patents be considered to be subject matter developed by Brough et al and owned by the assignee because they correspond to prior art teachings. Wang et al teach the use of deleted E1 and/or deleted E4 adenoviruses as vectors for gene delivery (for example, page 715, columns 2-3). Hardy teaches an adenovirus vector containing deletions of E1, E2, E3, and E4, and using CMV promoters, useful for gene therapy (abstract; columns 4-5, and Figure 3). Palmiter et al teach the use of LCR elements in adenovirus vectors (for example, column 11, and throughout the reference). Accordingly, the art rejection of record is dropped only for claims 13-14. Now, claims 13-14 are objected to because they depend on claims that remain rejected. It should be noted that the claim for exclusion of the Brough et al patents should have been made in response to the first action, at which time these references could have been timely applied. Finally, the applicant argues that Brough et al (newly cited Journal of Virology article) teaches away from the claimed invention drawn to the E1 and E4 deletion, because this reference teaches that there is lower sustained expression levels. This argument is not persuasive because persistent gene expression is not necessarily required for all applications of the claimed invention and that higher persistent gene expression has to be weighed against the art-recognized advantage of E4 deletion, such as the deletion of E4 being especially important to the ultimate design of safe adenovirus vectors (as taught by the applicant's cited reference at page 9206, column 2). Also, the Hardy and Palmiter et al references cited above teach the advantages of having E1, E4, etc deletions. This shows that in the balance, the prior art does teach why one of ordinary skill in the art would use these deletions despite one aspect of the E4 deletion being negative. The prior art must be considered as a whole in determining obviousness of the claimed invention and in whole, it would have been obvious to use these adenovirus deletions for reasons of record.